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In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1041V

UNPUBLISHED

LORY MAHAN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: December 17, 2021 Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Catherine Elizabeth Stolar, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On July 17, 2018, Lory Mahan filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on September 7, 2016. Petition, ECF No. 1 at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the vaccination alleged as causal was likely administered in Petitioner's right deltoid, and that the onset of Petitioner's shoulder injury occurred within 48 hours of her vaccination.

I. Relevant Procedural History

As noted above, the case was initiated in July 2018. On August 21, 2019, Respondent filed his Rule 4(c) Report. ECF No. 31. Respondent specifically maintained that Petitioner had not established receipt of a covered vaccine in her injured right shoulder, because Petitioner's flu vaccine was administered in her *left* shoulder. *Id.* at 5-6 (citing Ex. 1 at 1, Petitioner's vaccine administration record). Respondent also argued that the evidence preponderated against a finding that the onset of Petitioner's shoulder pain occurred within 48 hours of her vaccination as required by the Vaccine Injury Table. *Id.* at 6-7 (citing 42 C.F.R. § 100.3(a) (XIV) (B) (requiring onset of SIRVA within 48 hours after flu vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI). And Petitioner had not provided evidence sufficient to establish causation-in-fact under the relevant standard. *Id.* at 7-8.

Thereafter, former Chief Special Master Dorsey (who was then responsible for SPU cases) directed Petitioner to file a supplemental affidavit, and further directed the parties to file any additional evidence regarding the contested issues in this case. Subsequently, Petitioner sought and obtained by service of a subpoena an affidavit from Petitioner's vaccine administrator.[3]

On June 30, 2020, after a status conference with the parties' counsel, I issued a scheduling order setting a briefing schedule to resolve the factual issues in this case. ECF No. 40. Petitioner filed her brief, or Motion for a Fact Ruling on the Record, on October 28, 2020. ECF No. 45. Petitioner argued that she has established by preponderant evidence that she received her flu vaccine in her right shoulder, and that she experienced the onset of right shoulder symptoms, to include pain, within 48 hours of her vaccination. Respondent filed a Response to Petitioner's brief on November 30, 2020 disputing Petitioner's contentions. ECF No. 47. Petitioner filed a Reply brief on December 7, 2020. ECF No. 48.

[3] On May 26, 2020, Petitioner filed an affidavit from Brenda Crumb a registered nurse who administered Petitioner's vaccination, however, Ms. Crumb averred that she had no personal recollection of Petitioner, nor did she recall administering her flu vaccination. Ex. 15 at 2.

II. Issue

At issue is whether (a) Petitioner received the vaccination alleged as causal in her injured right shoulder, and (b) whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) (XIV)(B) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events

when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record to include all medical records, affidavits, testimony, expert reports, respondent's Rule 4 report, and additional evidence filed. Specifically, I base the findings on the following medical record evidence:

- Petitioner, a nurse, received a flu vaccine from her employer, Heywood Hospital, on September 7, 2016. Ex. 1 at 1. A box corresponding to "Deltoid Left" is checked off on Petitioner's vaccine consent form as the "Site of Injection." *Id.*

- On September 22, 2016, Petitioner was seen at by, Gene Del Rosario, MD, who documented that she had seen her cardiologist for a stress echocardiogram and noted Petitioner's "strong family history" of

cardiovascular disease. Ex. 7 at 35. There is no reference to Petitioner's vaccination or shoulder pain in this record.

- On October 4, 2016, less than one month after her vaccination, Petitioner saw Dr. Del Rosario again, this time for the chief complaint of "[r]ight shoulder pain" and reported that on September 7, 2016 she "received [her] flu vaccine," that "it was injected higher up [her] shoulder" and "hurt" a "normal soreness" for two weeks but was "now more painful" with decreased range of motion as a result of her pain. Ex. 2 at 12.

- Petitioner indicated that she had been taking 800 mg of ibuprofen which temporarily helped ease her symptoms. She also reported that she had done "computer research" regarding '"bursitis' by injection" and requested an MRI to "see the 'fluid.'" *Id.*

- Dr. Del Rosario examined Petitioner and assessed her with right shoulder pain, right impingement syndrome, and shoulder bursitis. *Id.* at 11-12. Dr. Del Rosario indicated in his opinion an MRI was not "necessary at this time" and he referred Petitioner to orthopedics for a cortisone injection evaluation. *Id.* at 11.

- On October 7, 2016, Petitioner was seen by orthopedist, Michael Azzoni, MD, for right shoulder pain. Ex. 2 at 13. Dr. Azzoni notes that Petitioner presented with complaints of right shoulder pain and reported a history of receipt of "a flu shot to the R[ight] shoulder on 9/7/16 which gave her pain initially." Ex. 2 at 14. Petitioner further reported the "pain and stiffness in the shoulder increased greatly" about a week prior, that she was having "difficulty with overhead motions," and "NSAIDs alleviate her pain." *Id.*

- Dr. Azzoni's October 7, 2016 record indicates that the "patient clearly states the injection was given to this [sic] right shoulder and she localized it fairly high and near subacromial location . . . . I think there is a possibility that indeed the injection could've actually gone into her subacromial space and the bursal area and resulted in this stiffness bursitis type picture." Ex. 2 at 14.

- Dr. Azzoni further indicates that "[t]he apparent documentation from the injection stated that it was given in the left shoulder and I think there is a possibility that [as] the patient clearly seems reliable and may be right that [the vaccination] was given to the right shoulder." Ex. 2 at 14.

- Dr. Azzoni assessed Petitioner with "shoulder bursitis with mild stiffness restriction [status post] the flu shot incident on 9/7/16." *Id.*

- Petitioner's subsequent medical records are consistent in documenting that the onset of her right shoulder pain followed the administration of a flu vaccine in her right shoulder on September 7, 2016. *See e.g.*, Ex. 2 at 1-2, 6-7; Ex. 8 at 3-5; Ex. 3 at 37-39.

Petitioner has offered two of her own sworn affidavits, in addition to affidavits of two co-workers, in support of the receipt of her September 7, 2016 vaccination in her right shoulder and her subsequent immediate onset of pain. Exs. 4-6, 14. Petitioner, a nurse of 20 years' experience, recalled that her September 7, 2016 flu vaccine was given high in her right arm. Ex. 14 at ¶ 6. Petitioner indicated in her affidavit testimony that she is left-handed and always receives her vaccinations in her right shoulder. Ex. 4 at ¶ 3. Petitioner also maintains that her pain was immediate following her vaccination, and that her shoulder has never felt the same since. Ex. 14 at ¶¶ 6-7. Petitioner indicated that she did raise the issue of shoulder pain at her September 22, 2016 visit with Dr. Del Rosario, but she did so "casually" as she believed at that time her pain would improve. Ex. 14 at ¶ 9.

The affidavits of Petitioner's coworkers, Nancy Gyles and Karen Wrigley, who have known and worked with Petitioner at Heywood Hospital for many years, state that Petitioner complained to them both the same day she received her flu vaccine of pain in her right arm. Ex. 5 at ¶ 4, Ex. 6 at ¶ 5. Ms. Gyles recalled Petitioner recounting to her that the vaccination was administered too high in her right shoulder, and that Petitioner rubbed her right shoulder arm while they were talking. Ex. 5 at ¶ 4. Ms. Wrigley, who also received a flu vaccine that same day, specifically recalls that Petitioner showed her right arm to her and pointed to the spot where she received her vaccination. Ex. 6 at ¶ 5. Ms. Wrigley recounted that Petitioner continued to complain of right shoulder pain for weeks thereafter, and that she herself could observe that Petitioner was in pain during their shifts. *Id.* at ¶ 6. Both co-workers also noted that they are familiar with the fact that Petitioner is left-handed and never receives vaccinations in her left arm. Ex. 5 at ¶ 5, Ex. 6 at ¶ 5.

The medical entries discussed above (as supported by the affidavit testimony) support the conclusion that Petitioner likely received the flu vaccination in her right deltoid on September 7, 2016, as alleged, and that she suffered the onset of shoulder pain in her right shoulder within 48 hours of her vaccination.

On the situs issue, Respondent argues that the vaccine consent form resolves the question of left versus right arm. I find, however, that such evidence is overcome by Petitioner's contemporaneous treatment records for her shoulder injury, and the affidavits offered by Petitioner and her co-workers. In particular I rely upon the October 7, 2016 record of Petitioner's visit with her orthopedist, Dr. Azzoni – only one month after her vaccination – indicating that Petitioner presented with complaints of right shoulder pain and reported a history of receipt of "a flu shot to the R[ight] shoulder on 9/7/2016 which gave her pain initially." Ex. 2 at 14. Dr. Azzoni notes that the "patient clearly states the injection was given to this [sic] right shoulder and she localized it fairly high and near subacromial location." *Id.* More significantly, Dr. Azzoni was aware that Petitioner's

vaccine consent form indicated the vaccination was administered in her left shoulder and observes that "I think there is a possibility that [as] the patient *clearly seems reliable* and may be right that [the vaccination] was given to the right shoulder." *Id.* (emphasis added).

Respondent maintains that Petitioner's statements to her providers that she received the vaccination in her right shoulder constitute "claims of a petitioner alone, unsubstantiated by medical record or medical opinion," and asserts that I may not decide Petitioner's vaccination occurred in her right shoulder based on these statements which contradict her contemporaneous vaccination record. ECF No. 47 at 6 (citing Section 13(a)(1)). But Petitioner's medical records *do* substantiate her allegations, as they include contemporaneous proof not only of instances in which she claimed a right-sided vaccination, but a record explicitly discussing the accuracy of the administration form. Petitioner's affidavit evidence also provides context for why she would have sought vaccination in her non-dominant arm, and she also offers co-worker statements (from medical professionals) consistent with her contentions. Thus, the overall combination of evidence preponderantly supports her allegation.

Respondent's argument that Petitioner has not established onset of her shoulder pain within 48 hours of her vaccination is also unavailing. ECF No. 47 at 7-8. As support for his position, Respondent points out that Petitioner's medical records do not document her shoulder until a month after her vaccination. *Id*. at 7. Additionally, Respondent notes that the record from Petitioner's September 22, 2016 visit with Dr. Del Rosario, two weeks after her vaccination, does not document any complaints of shoulder pain. *Id*.

Both of these assertions are true as far as they go. But I find that Petitioner's treatment records from Dr. Del Rosario and Dr. Azzoni (beginning a month after her vaccination) clearly document that she consistently reported the onset of right shoulder pain as immediately following her September 7, 2016 vaccination. Ex. 2 at 11-14.[4] Based on my experience adjudicating SIRVA cases, a month delay before seeking treatment for a possibly vaccine-caused shoulder injury is a reasonable amount of time to have passed.[5] Additionally, I find that Petitioner's explanation in her supplemental affidavit,

[4] Respondent also asserts it is important for me to consider the fact that Petitioner had done "computer research' and thought she had "bursitis my injection" in advance of her October 4, 2016 visit. ECF No. 47 at 7, n. 3 (citing Ex. 2 at 12). But this information does not cause me to discount Petitioner's statements to her providers that she suffered shoulder pain following a flu vaccination in her right shoulder.

[5] As I have previously observed, in focusing on a gap in treatment

> Respondent seems to be arguing that the only way Petitioner can show she experienced symptoms within 48 hours of vaccination is with contemporaneous records created *within* that two-day timeframe. But the Vaccine Act clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe. 42 U.S.C. § 300aa-13. Of course, the

coupled with her background as a nurse, that she only mentioned her vaccination and shoulder pain in passing at her September 22, 2016 visit with Dr. Del Rosario (as she believed her shoulder symptoms would improve) is a reasonable explanation for why the record does not formally memorialize this statement.

Respondent also argues in his brief that Petitioner's reports that she had "normal soreness" following her vaccination, and thus her subsequent statements that her pain worsened after a few weeks suggest a true onset beyond the 48-hour window set by the Table. ECF No. 47 at 7-8. I note, however, that Petitioner explains in her affidavit that by "normal" she meant that it was a "pain level that she could tolerate," but that the pain was nevertheless "more severe than I had experienced with vaccinations in the past." Ex. 14 at ¶ 11. Thus, even if the pain progressed in severity over time, the record still preponderantly supports the conclusion that it began within the Table timeframe.

Therefore, and based upon the foregoing, I find there is preponderant evidence to establish (a) the vaccination alleged as causal in this case was administered to Petitioner in the right deltoid on September 7, 2016, and (b) the onset of Petitioner's pain occurred within 48 hours of her vaccination.

V. Scheduling Order

Respondent shall file a Supplemental Rule 4(c) Report, taking this Ruling into consideration, by no later than Tuesday, January 18, 2022. Thereafter, the parties will be given an opportunity to informally resolve damages in this case, but if that cannot be done in an expeditious manner, I will invite the parties to brief damages in this matter for my resolution.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

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reliability of onset evidence may hinge on when and how onset is recorded, and evidence of post-vaccination pain from a record created no more than two days post-vaccination would constitute particularly strong evidence of onset. But a petitioner can still prevail even if the evidence establishing onset comes from a later period. Ultimately, resolving how to weigh the evidence pro and con on such matters falls within the purview of the special masters. *Id.*

Niemi v. Sec'y of Health & Human. Servs., No. 19-1535V, 2021 WL 4146940, at *4 (Fed. Cl. Aug. 10, 2021). The same is true for evidence in regard to the site of vaccination, since it is not uncommon for the immediate administration records to be in error. Accordingly, the site of vaccination can be established even in the face of a contradictory vaccination record, with subsequent evidence in the contemporaneous treatment records and affidavit testimony.